UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,944	10/04/2001	John L. Herrmann	21402-138 (CURA-438)	3505

30623 7590 05/03/2004

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,944	HERRMANN, JOHN ET AL	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 1950*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4,38, and 41, drawn to an isolated polypeptide, a pharmaceutical composition, and a kit, classified in class 514, subclass 2. Note if applicant elects this group for prosecution on the merits, applicant is required to select an amino acid sequence from SEQ ID Nos: 2,4,6,8,10, and 12 and its corresponding nucleic acid sequence from SEQ ID Nos: 1,3,5,7,9, and 11. This election should not be construed as an election of species, see paragraph 8 below for explanation.

II. Claims 5-14, 39, and 42, drawn to an isolated nucleic acid, a vector comprising said nucleic acid, a cell, a pharmaceutical composition comprising the nucleic acid, and a kit, classified in class 536, subclass 23.1. Note if applicant elects this group for prosecution on the merits, applicant is required to select a nucleic acid sequence from SEQ ID Nos: 1,3,5,7,9, and 11 and its corresponding amino acid sequence from SEQ ID Nos: 2,4,6,8,10, and 12. This election should not be construed as an election of species, see paragraph 8 below for explanation.

III. Claims 15-17, 40, and 43, drawn to an antibody specific for ONE of the peptides listed in group I, a pharmaceutical composition comprising said antibody, and a kit classified in class 530, subclass 387.1.

IV. Claim 18, drawn to a method of determining the presence or amount of the polypeptide of group I, classified in class 435, subclass 7.1.

V. Claims 19-21, drawn to a method of determining the presence or amount of the nucleic acid of group II, classified in class 435, subclass 6.

VI. Claims 22-23, drawn to a method of identifying an agent that binds to the polypeptide of group I, classified in class 435, subclass 4.

VII. Claim 24, drawn to a method of identifying an agent that modulates the expression or activity of the polypeptide of group I, classified in class 435, subclass 4.

VIII. Claim 25, drawn to a method of modulating the activity of the polypeptide of group I, classified in class 514, subclass 1.

IX. Claims 26-29, and 48 drawn to a method of treating or preventing a NOVX-associated disorder comprising the administration of the polypeptide of group I and a method of treating a pathological state in a mammal comprising the administration of a polypeptide comprising the amino acid sequence of at least one of SEQ ID No: 2,4,6,8,10, and 12, classified in class 424, subclass 184.1. Note if applicant elects this group for prosecution on the merits, applicant is required to select an amino acid sequence from SEQ ID Nos: 2,4,6,8,10, and 12 and its corresponding nucleic acid sequence from SEQ ID Nos: 1,3,5,7,9, and 11. This election should not be construed as an election of species, see paragraph 8 below for explanation

X. Claims 30-33, drawn to a method of treating or preventing a NOVX-associated disorder comprising the administration of the nucleic acid of group II, classified in class 514, subclass 44.

XI. Claims 34-37 and 49-50 drawn to a method of treating or preventing a NOVX-associated disorder comprising the administration of the antibody of group III and a method of treating a pathological state in mammal comprising the administration of an antibody of group III, classified in class 424, subclass 137.1.

XII. Claims 44-45, drawn to a method of determining the presence or predisposition to a diseases comprising the measuring of the levels of the polypeptide of group I, classified in class 424, subclass 9.1 and class 436, subclass 64.

XIII. Claims 46-47, drawn to a method of determining the presence or predisposition to a disease comprising the measuring of the nucleic acid of group II, classified in class 536, subclass 23.1 and class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions differ one from the other in that the structural and chemical make-up of the products are different and distinct. The inventions of group I-III are polypeptides, nucleic acid, or antibodies all of which are structurally distinct and have different functional activities.

3. Inventions IV-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other in that the methods all have distinct steps, require different components, and are use for different purposes. For instance, the inventions of groups IV, VI-IX, and XII are methods involving polypeptides, all of which are used for distinct purposes, such as expression profiling, screening for agents, modulation of activity, and treatment of disease and which do not involve the use of either nucleic acids or antibodies. The inventions of groups V, X, and XIII involve the use of nucleic acids which do not use either polypeptides or antibodies, and the inventions of groups XI involve the use of antibodies which do not require the use of polypeptide or nucleic acids.

4. Inventions I and IV, VI-IX, and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

methods can be accomplished using either antisense nucleic acid molecules or by using antibodies.

5. Inventions II and V, X, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods can be accomplished using polypeptides or antibodies.

6. Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods can be accomplished by using antisense of specific peptides that are capable of binding to the target.

7. Because these inventions are distinct for the reasons given above and the search required for Group I-XIII are not required one for the other, restriction for examination purposes as indicated is proper.

8. Upon election of Group I or II, Applicants are additionally required to elect a single Sequence identified by a specific sequence identification number, as indicated above as they apply to group(s). The recited sequences have different structures one from other and the search for the sequences would be unduly burdensome. This

requirement is not to be construed as a requirement for an election of species, since each of the sequence(s) recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

i. If applicant elects group IX for prosecution on the merits, applicant must elect either *cardiomyopathy, atherosclerosis, signal processing,* or, *metabolic pathway modulation* as the initial species for search purposes.

ii. If applicant elects group XI for prosecution on the merits, applicant must elect either *signal processing,* or *metabolic pathway modulation* as the initial species for search purposes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27-28, and 36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
April 19, 2004

GARY NICKOL
PRIMARY EXAMINER